stryker® ENDOSCOPY

SEP 2 8 2001

K012270

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Smooth or Threaded Metallic Bone Fixation Fasteners: 21 CFR §888.3040, Class II
Common and Usual Name:	Threaded Fixation Pin (87 JDW)
Proprietary Name:	Stryker Cross-Pinned Interference Screw

Predicate Device

Stryker Wedge Interference Screw (#K972233) currently marketed by Stryker Endoscopy (Santa Clara, CA).

Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker Cross-Pinned Interference Screw is intended for use in the surgical reconstruction of the anterior cruciate ligament (ACL) deficient knee to provide interference fixation of the various ACL allografts and autografts, including the patella bone-patellar tendon-tibial bone graft complex, the semi-tendinosus tendon graft, the semi-membranosus tendon graft, and the Achilles tendon graft. The interference screw fixation technique is a common method in orthopedic surgery, and has been well published in professional journals such as *Arthroscopy: The Journal of Arthroscopic and Related Surgery.*

The Stryker Cross-Pinned Interference Screw consists of an implant and associated instruments for installation of the implant. The implant consists of two components: an interference screw and a cross pin. The interference screw has a transverse hole in it for receipt of the cross pin. The cross pin is available for optional use by the user, in the event that adjunctive fixation is deemed appropriate. A drill guide provides alignment for drilling a hole coincident with the hole in interference screw and for receiving the cross pin.

Both implants will be provided sterile for single-use applications (ASTM 4169). These devices will be sterilized by Gamma irradiation (EN 552) or Ethylene oxide (EN550), including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6}. The devices are biocompatible per ISO-10993 and G95-1. The Stryker Cross-Pinned Interference Screw is equivalent in intended use, safety, and efficacy to the predicate device. The cadaver testing showed a significant strength increase of both the yield load and the ultimate load. The material of construction is Ti-6Al-4V ELI per ASTM F136.

The Stryker Cross-Pinned Interference Screw System does not raise new issues when compared to the currently marketed predicate device. Therefore, it is considered substantially equivalent to the Stryker Wedge Interference Screw System.

Contact:

Alisa Miller
Quality Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, CA 95051
(408) 567-9100 x.2259

Date: July 10, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

Ms. Alisa Miller
Quality Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

Re: K012270
Trade/Device Name: Stryker Cross-Pinned Interference Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDW
Dated: July 10, 2001
Received: July 19, 2001

Dear Ms. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Divison of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

June 22, 2001

510(k) Number if known: K012270

INDICATION FOR USE:

The Stryker Cross-Pinned Interference Screw System is intended for use in the surgical reconstruction of the anterior cruciate ligament (ACL) deficient knee to provide interference fixation of the various ACL allografts and autografts, including the patella bone-patellar tendon-tibial bone graft complex, the semi-tendinosus tendon graft, the semi-membranosus tendon graft, and the Achilles tendon graft.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012270